K030618

9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 27 2003

Submitted By:
Margaret J. Posner, Regulatory Affairs Specialist
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105-4191
336.744.0157

Names of Device:

Trade Name:	Wilson-Cook Celiac Plexus Neurolysis Needle
Common/Usual Name:	Celiac Plexus Neurolysis Needle
Classification Name/Code:	Needle, Aspiration and Injection, Disposable; 21 CFR § 878.4800 (GAA); Class II

Predicate Devices:
The Wilson-Cook Celiac Plexus Neurolysis Needle is comparable to predicate devices including the Wilson-Cook Variable Length GI Injection Needle (K941305), the Wilson-Cook Endoscopic Ultrasound Needle (K934356), and the InjecTx PercuTx- Injection/Aspiration Needle Probe/Device (K994151).

Device Description:
The Wilson-Cook Celiac Plexus Neurolysis Needle is comprised of a stainless steel echogenic pencil point needle with four side openings toward the tip. The handle allows a stroke of approximately 8-cm to advance the needle into position. The outer sheath of the device is comprised of polytetrafluoroethylene.

Intended Use:
The Wilson-Cook Celiac Plexus Neurolysis Needle is used to deliver neurolysing agents to the celiac plexus under guidance by endoscopic ultrasound. It is supplied sterile and is intended for single use only.

Substantial Equivalence:
The Wilson-Cook Celiac Plexus Neurolysis Needle is comparable to predicate devices with similar technological characteristics and intended use, specifically to perform endoscopic injection procedures.

Discussion of Tests and Test Results:
The Wilson-Cook Celiac Plexus Neurolysis Needle underwent simulated use testing and clinical evaluation. Test results provide reasonable assurance the device will perform in accordance with its intended use.

Conclusion:
Being similar to predicate devices with respect to intended use and technology, and having test results that indicate the device will perform in accordance with its intended use, the Wilson-Cook Celiac Plexus Neurolysis Needle meets the requirements for 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2003

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, North Carolina 27105-4191

Re: K030618
Trade/Device Name: Wilson-Cook Celiac Plexus Neurolysis Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG, GAA
Dated: February 14, 2003
Received: February 26, 2003

Dear Ms. Posner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

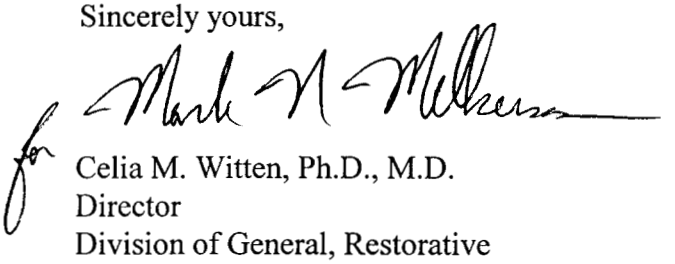
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030618

Device Name: Wilson-Cook Celiac Plexus Neurolysis Needle

Indications For Use:

The Wilson-Cook Celiac Plexus Neurolysis Needle is used to deliver neurolysing agents to the celiac plexus under guidance by endoscopic ultrasound. It is supplied sterile and is intended for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030618

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)